MECHANICAL AND VISCO-ELASTIC PROPERTIES OF UHMWPE FOR *IN-VIVO* PRODUCT DEVELOPMENT

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Abstract

Ultra-high molecular weight polyethylene (UHMWPE) is used in orthopedic applications within the human body. Components made from these materials are subject to complex loading over extended periods of time. Modeling of components used in such applications depends heavily on having material data under *in-vivo* conditions. We present mechanical and visco-elastic properties measured in saline at 37C. Comparisons to conventionally measured properties at room temperature are presented.

Introduction

Polymers are seeing increasing use inside the human body. Biomedical applications range widely from orthopedic implants, catheters, lenses, artificial blood vessels to stents and in-vivo devices such as pacemakers. These are demanding applications where the polymer may conceivably need to face a hostile environment with a high degree of reliability. It is therefore of critical importance that the behavior of polymers used *in-vivo* applications is completely understood. Both the short term as well as the long-term characteristics must be studied in detail before these materials are incorporated into biomedical products.

Almost all mechanical properties of polymers that are easily available from material suppliers and from open sources on the Internet are measured at room temperature. Since the human body is at 37C, it would seem reasonable to assume that the properties do not change much over such a small temperature range. An additional variable of the human body is that the polymers are immersed in body fluids. This fluid environment can also affect the behavior of the polymer. Because testing in fluid environments is difficult, again, it is often convenient to assume that fluid does not affect the properties. However, because of the critical nature of biomedical applications, it is necessary to test the validity of these assumptions.

In our paper, we select a typical material that can be used in biomedical applications and measure properties that describe the quasi-static as well as the long-term characteristics at ambient and *in-vivo* type conditions. In doing so, we provide a quantification of the validity of the assumptions presented above. With this, biomedical engineers can have a better feel for the loss in properties when designing with this plastic. Additionally, we create a basic methodology for the characterization of polymers used *in-vivo* applications.

Materials

For the purpose of our study, we selected an Ultra-high molecular weight polyethylene (UHMWPE) polymer. Samples were obtained as extruded sheets from McMaster Carr Supply Company (#8752K111). Samples were assumed to be isotropic in nature and were 3.2 mm thick. For the tensile experiments, ASTM D 638 Type V tensile bars were machined using CNC methods. These specimen types were selected for their short length, which was needed to ensure complete immersion in the saline cell during the measurement. For the visco-elastic experiments, 13.5mm wide straight-sided specimens were used. The DatapointLabs sample identification number was 16176.

The saline solution used for the experimentation was a Fend-All Eyesaline® eyewash solution which according to the manufacturer, is physiologically similar to human tears.

Equipment

Tensile tests were performed on an Instron 5566 universal testing machine (UTM) equipped with a temperature-controlled oven. Strain was measured using an 8 mm contact extensometer.

For the saline experiments, a saline cell was constructed to ensure that the specimen was completely immersed during the tests. The temperature of the cell was controlled at 37C by using a loop from a circulator. Strain for the saline experiments was calculated using an inference method described by Perkins and Lobo [1].

Visco-elastic measurements were performed using a BOSE Enduratec ELF 3200 machine. The instrument was configured for tensile stress relaxation type experiments. The same saline cell described above was used for the saline visco-elastics measurements.

Experimental Details

The tensile testing was conducted at a crosshead speed of 5 mm/min. For each case, two test specimens were pulled beyond yield and stress-strain curves were obtained. Tensile modulus and yield stress and strain were calculated using methods prescribed in ASTM D638.

Testing was carried out in air at 23 and 37C. Additionally, tests were carried out at 23 and 37C on specimens while they were immersed in the saline cell. The test specimens used in the saline testing had been previously soaked in saline at room temperature: for visco-elastic experiments, after 2 weeks soaking in saline; tensile properties were measured after 30 days of soaking.

For the visco-elastic measurements, identical tensile stress relaxation measurements were made in air and immersed in saline to determine the effect of saline on the long-term properties.

Each stress relaxation test was carried out at an imposed strain of 0.5% for a period of 10,000 sec. Tests were conducted at 23, 37, 43, 52 and 63C. Resulting stress relaxation curves were shifted to a master curve using time-temperature superposition methods described in detail by Neilsen and Landel [2].

All data was uploaded to the Matereality Global Data Center (www.matereality.com) for visualization and analysis and the properties shown in the paper are available in digital form there.

Results and Discussion

A measurable reduction in quasi-static mechanical properties was noted at between ambient and 37C in air measurements (Fig. 1).

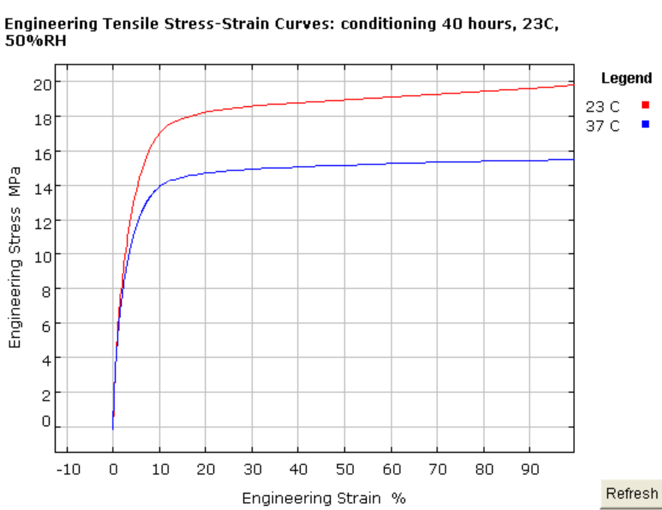

Figure 1 Effect of temperature on stress-strain properties of virgin UHMWPE

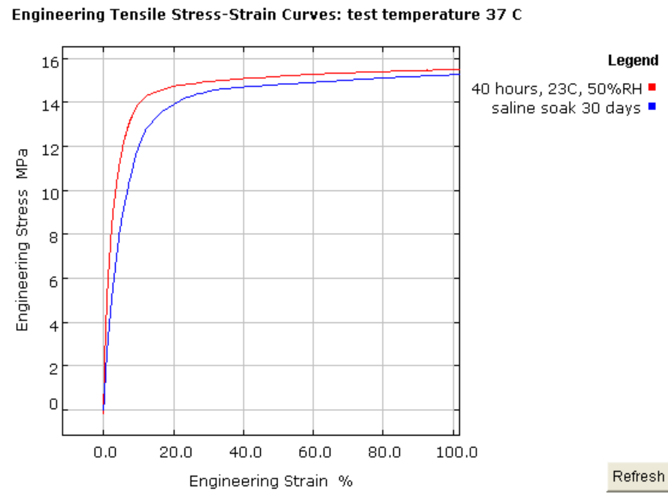

Figure 2 Effect of saline environment on stress-strain data on UHMWPE at 37C

Reductions were observed in both the modulus as well as the tensile strength at yield. Figure 2 shows a comparison of test data taken at 37C on virgin and saline soaked UHMWPE where a significant lowering in stiffness with saline exposure is noted. Figure 3 is the same as Figure 1, but for the saline soaked material. The plots are remarkably similar except for the lowered stiffness of the saline soaked UHMWPE. Table 1 compiles these effects.

Table 1: Tensile properties of UHMWPE

Property	23C Air	23C Saline	37C Air	37C Saline
Modulus (MPa)	763	390	658	306
Strength (MPa)	18	17	14	14
Poisson's Ratio	.317		.355	

It appears that the tensile strength at yield is more greatly affected by temperature than by the immersion in saline solution, with substantially no change being noted due to immersion. In contrast, the modulus of the saline soaked specimens is half that of the virgin material. This effect is also noted qualitatively in the visco-elastic data where the soaked material has a lower instantaneous modulus than the virgin polymer.

Some change in the Poisson's Ratio is observed with temperature. The effect of saline immersion was not measured.

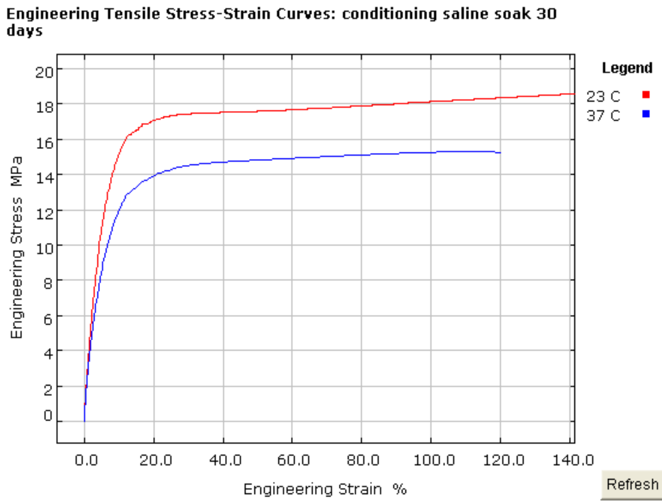

Figure 3 Effect of temperature on stress-strain properties of saline soaked UHMWPE

The visco-elastic measurements showed some interesting results. The tensile stress relaxation modulus v. time master curve obtained after time- temperature superposition is seen to be different between virgin and saline soaked specimens. While both specimens appear to have a relatively similar instantaneous modulus, the saline-exposed specimen shows a greater modulus decay than the unsoaked specimen; further while the specimen in air shows a trend toward a long-term modulus at around 60MPa, the saline exposed specimen continues to dip downward below 20MPa.

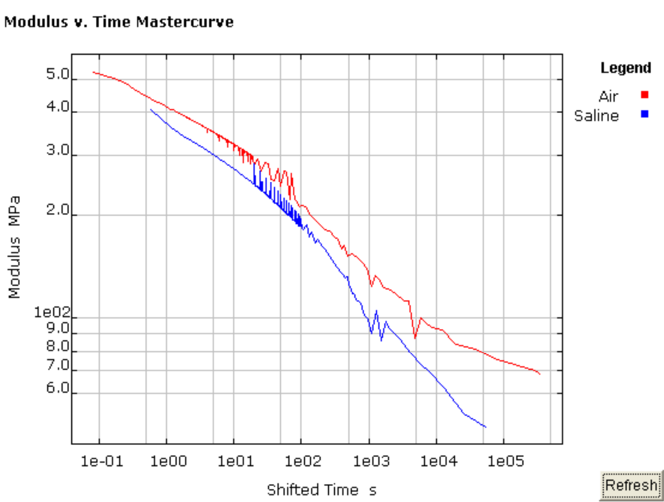

Figure 4 Stress relaxation mastercurve for UHMWPE

It is important to note that in the interpretation of the visco-elastic properties, particularly for use in design and CAE, that modulus be interpreted as relative and not an absolute value. While theoretically, visco-elastic measurements should yield modulus measurements with the same accuracy as tensile stress-strain measurements, practical considerations prevent this from being so. First, visco-elastic measurements use straight-side test specimens as against the tensile bars used in tensile experiments. Strain here is measured via crosshead displacement and may contain artifact from the gripping of the test specimen, as well as suffer from the lower accuracy of the crosshead displacement measurement transducer (LVDT). In contrast, tensile experiments use contact extensometry; here the strain is precisely measured free from artifact. Consequently, there may not be a perfect match in modulus between the two types of experiments; stress-relaxation data is often normalized before use.

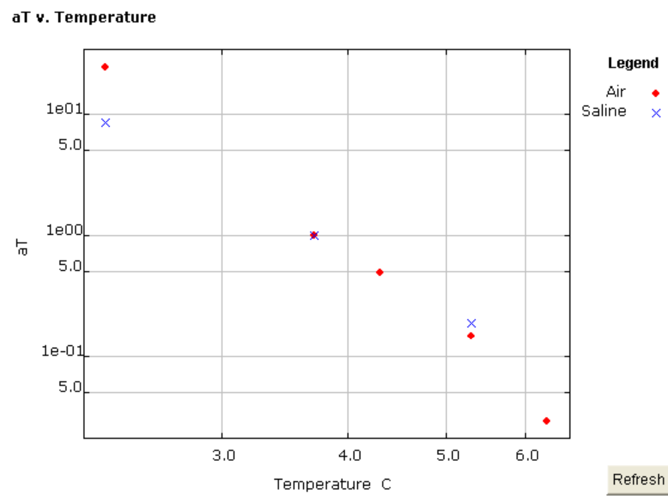

Figure 5 Shift factors for master curve of UHMWPE

The shift factors appear to be insensitive to the saline soak suggesting that the scaling of the master curves with temperature is not affected by whether or not the material is in saline.

Conclusions

In the case of the polymer studied, both the quasi-static and visco-elastic material properties are observed to change significantly with saline immersion. This is an unexpected outcome considering the non-hygroscopic nature of polyolefins. The effect is complex in that tensile strength at yield is affected by temperature while the modulus is lowered by saline immersion. Visco-elastically, the saline immersed polymer decays in modulus to a greater extent than virgin polymer.

We believe that this work illustrates the necessity of measuring material properties under the conditions of use. In this case, the material in its use environment has markedly different properties that can affect design decisions. Our approach could serve as a model for investigation of the mechanical properties of bio-medical polymers that are used *in-vivo* environments.

Acknowledgements

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References

1. Perkins, L., Lobo, H., SPE ANTEC Proceedings, Boston (2005)
2. Neilsen, L.E., Landel, R.F., “Mechanical Properties of Polymers and Composites”, 2nd Ed. Marcel Dekker, Inc. New York, (1994)